NSF International

Joint Committee Correspondence

TO: Joint Committee on Dietary Supplements

FROM: Brian Zamora, Chairperson

DATE: September 7, 2018

SUBJECT: Proposed revision to NSF/ANSI 173 – *Dietary Supplements* (173i68r1)

Draft 1 for NSF/ANSI 173, Issue 68 is presented to the Joint Committee on Dietary Supplements for consideration. Please review the changes proposed to this standard and submit your ballot by **the due date of September 28, 2018** via the NSF Online Workspace <www.standards.nsf.org>.

When adding comments, please include the section number applicable your comment and add all comments under one comment number whenever possible. If additional space is needed, you may upload a word or .PDF version of your comments online via the browser function.

Purpose

This proposal is intended to clarify the requirements of section 6.1.1 for identification test methods for botanicals, as the selection of appropriate methods is highly dependent on the type of sample being identified.

Background

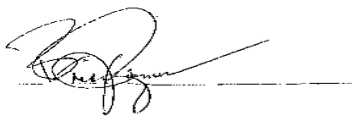
The dietary supplement industry is currently undertaking several voluntary initiatives to bring attention to the importance of supply chain management and the proper identification of botanical species used to product ingredients for these products. This topic extends to the appropriateness of the analytical techniques used to make the botanical identification.

This proposal is intended to clarify the requirements of section 6.1.1 for identification test methods for botanicals, as the selection of appropriate methods is highly dependent on the type of sample being identified.

Public Health Impact

These changes will have no negative impact on public health.

If you have any questions feel free to contact me.



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[Note – the recommended changes to the standard which include the current text of the relevant section(s) indicate deletions by use of ~~strike-out~~ and additions by grey highlighting. Rationale Statements are in *italics* and only used to add clarity; these statements will NOT be in the finished publication. Please also note that formatting of the document will be finalized by the Standards Dept. prior to publication.]

NSF International Standard
for Dietary Supplements —

Dietary supplements

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6 Test methods used by testing laboratories for identification and quantification of ingredients – dietary ingredients and finished products

6.1 Identification test methods

6.1.1 Botanicals

The identity of botanical dietary ingredients shall be verified with one or more tests or examinations in accordance with the most appropriate analytical method(s) as described in 6.1.1.1 through 6.1.1.3. The selected test(s) or examination(s) shall be performed by an appropriately qualified individual using documented procedures, and shall be scientifically valid and fit for the purpose of analysis of the specific sample type being tested. Selection of the test method(s) shall consider the least burdensome analytical approach necessary to confirm identity of the specific sample being verified.

6.1.1.1 Macroscopic and organoleptic/sensory evaluation

Macroscopic and organoleptic/sensory test methods used for verifying ~~T~~the identity of unprocessed botanical dietary ingredients (whole plants or identifiable plant parts) shall be ~~evaluated~~ based on the information contained in applicable monographs (AHP, BHP, EP*; PPRC*; USP and other compendial references; except that, when no applicable compendial monograph exists, the qualified individual shall confirm identity based on the information contained in one or more alternative scientific references developed based on well-established principles of macroscopic assessment such as are presented in classic botanical pharmacognosy literature, and shall identify and record the alternative reference(s) used.

*******NOTE (This is for clarity only not for consideration in the standard): The two additional compendial references identified here are not yet included in 173's Normative References; this Issue Paper is peripherally proposing the current editions of these two documents be added to the Normative References – the European Pharmacopoeia (EP) and the Pharmacopoeia of the People's Republic of China (PPRC).***

6.1.1.2 Microscopic test methods

Microscopic test methods used for verifying ~~T~~the identity of non-extract botanical ingredients (whole plants, identifiable plant parts, cut or powdered forms) shall be ~~evaluated~~ based on the information contained in applicable monographs (AHP, BHP, EP*, PPRC*, USP and other compendial references; except that, when no applicable compendial monograph exists, the qualified individual shall confirm identity based on the information contained in one or more alternative scientific references developed based on well-established principles of microscopic assessment such as are presented in classic botanical pharmacognosy literature, and shall identify and record the alternative reference(s) used.

6.1.1.3 Chemical test methods

Chemical test methods used for verifying ~~T~~the identity of botanical dietary ingredients (all forms) shall be ~~evaluated using methods that are scientifically valid and suitable for the intended purpose. Sources for methods should include~~ based on the information contained in applicable references (AOAC International, AHP, USP, EP*, PPRC*, and other method sources); except that ~~Modification~~ modification of an existing method to better suit the sample under test is allowable~~. If~~, and if no appropriate method exists development of a new method is allowable. The use of any modified or new method shall require that an assessment be performed which includes evaluation of the method specificity.

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